p1 of 4

STERIS®

AUG 18 2011

510(k) Summary
For
Amsco® V-PRO™ 1 and V-PRO™ 1 Plus Low Temperature Sterilization Systems

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Submission Date: July 27, 2011

K102394
p2 of 4

1. Device Name

Trade Name:	Amsco V-PRO 1 Low Temperature Sterilization System and Amsco V-PRO 1 Plus Low Temperature Sterilization System
Common/usual Name:	Vapor Phase Hydrogen Peroxide Sterilizer
Classification Name:	Sterilizer, Ethylene Oxide Gas
Classification Number:	21 CFR 880.6860
Product Code:	MLR

2. Predicate Device

Amsco® V-PRO™ 1 Low Temperature Sterilization System (K062297)

Amsco® V-PRO™ 1 Plus Low Temperature Sterilization System (K083097)

3. Description of Device

The Amsco V-PRO 1 and V-PRO 1 Plus Low Temperature Sterilizers are self-contained stand-alone devices using vaporized hydrogen peroxide. These devices are intended for use in terminal sterilization of cleaned, rinsed and dried, reusable medical devices used in healthcare facilities. The sterilizers operate at low pressure and low temperature and are therefore suitable for processing medical devices sensitive to heat and moisture.

4. Intended Use

The Amsco V-PRO 1 and V-PRO 1 Plus Low Temperature Sterilization Systems, with VAPROX HC Sterilant, are vaporized hydrogen peroxide sterilizers intended for use in the terminal sterilization of cleaned, rinsed and dried reusable metal and nonmetal medical devices used in healthcare facilities. The pre-programmed sterilization cycles operate at low pressure and low temperature and are thus suitable for processing medical devices sensitive to heat and moisture.

The V-PRO 1 Cycle, which is identical to the V-PRO 1 Plus Lumen Cycle, was cleared under K062297 and can sterilize:*

- Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors
- Medical devices with a single stainless steel lumen with:
  - an inside diameter of 1 mm or larger and a length of a 125 mm or shorter

- an insider diameter of 2 mm or larger and a length of 250 mm or shorter
- an inside diameter of 3 mm or larger and a length of 400 mm or shorter

* The validation testing for all lumen sizes was conducted using a maximum of twenty (20) lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing. The validation studies were performed using a validation load consisting of two instrument trays and two pouches for a total weight of 19.65 lbs.

The Amsco V-PRO 1 Plus Low Temperature Sterilization System's Non Lumen Cycle was cleared under K083097 and can sterilize:**

Non-lumened instruments including non-lumened instruments with stainless steel diffusion-restricted areas such as the hinged portion of forceps or scissors.

** The validation studies were conducted using a validation load consisting of two instrument trays and two pouches for a total weight of 19.65 lbs.

5. Description of Safety and Substantial Equivalence

The Amsco V-PRO 1 and V-PRO 1 Plus Low Temperature Sterilization Systems are the same as the predicate devices (K062297 and K083097) except for a proposed change to the device Operator Manual to include polyether ether ketone (PEEK) as a compatible material for the V-PRO 1 Cycle and V-PRO 1 Plus Lumen and Non Lumen Cycles; and polyurethane as a compatible material for the V-PRO 1 Plus Non Lumen Cycle. These proposed labeling changes to add these materials as compatible with VAPROX HC Sterilant do not affect the design or performance specifications of the devices and no new concerns arise regarding the safety and effectiveness when compared to the predicate devices.

The following table summarizes the verification activities that were performed with their respective acceptance criteria to ensure the safety and effectiveness of processing PEEK-containing materials in the V-PRO 1 Cycle and V-PRO 1 Plus Lumen and Non Lumen Cycles and polyurethane-containing materials in the V-PRO 1 Plus Non Lumen Cycle. Each test listed was completed for both polyurethane and PEEK.

The differences between the proposed and predicate device are limited to the described modifications of the device and these proposed changes raise no new concerns of safety and effectiveness when compared to the predicate device. The proposed Amsco V-PRO 1 and V-PRO 1 Plus Low Temperature Sterilization Systems are substantially equivalent to the predicate.

Test	Acceptance Criteria	Result
Biocompatibility	Cytotoxicity and residue analysis have demonstrated biocompatibility after processing in the V-PRO sterilizer	Pass
Material compatibility	Device maintains functionality following sterilization	Pass
½ Cycle sterilization efficacy	No survivors at ½ cycle condition with End Of Shelf Life Sterilant	Pass
Simulated Use evaluation	No survivors on device surface after processing with the V-PRO Non Lumen Cycle using EOSL sterilant	Pass
In Use evaluation	Sterile results on all polyurethane and PEEK containing devices	Pass

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Robert Sullivan
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AUG 18 2011

Re: K102394
Trade/Device Name: Amsco® V-PRO™ 1 Low Temperature Sterilization System and Amsco® V-PRO™ 1 Plus Low Temperature Sterilization System
Regulation Number: 21 CFR 880.6860
Regulation Name: Ethylene Oxide Gas Sterilizer
Regulatory Class: II
Product Code: MLR
Dated: July 27, 2011
Received: July 28, 2011

Dear Mr. Sullivan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Amsco® V-PRO™ 1 Low Temperature Sterilization System
Amsco® V-PRO™ 1 Plus Low Temperature Sterilization System

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Prescription Use _____ AND/OR Over-The-Counter Use ____X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K102394